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Aliphatic Alcohols, C1-C5
Interim Registration Review Decision Case Number 4003

September 2016

Approved by: _____

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Director
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I. Introduction

This document is the Environmental Protection Agency's (EPA or the agency) *Interim Decision* (ID) for aliphatic alcohols, C1-C5 (case 4003, PC codes 00150 and 1047501) and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may: 1) require new risk mitigation measures, 2) impose interim risk mitigation measures, 3) identify data or information required to complete the review, and 4) include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. Further information and additional documents on aliphatic alcohols, C1-C5 can be found in EPA's public docket (EPA-HQ-OPP-2012-0340) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically reevaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www2.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The aliphatic alcohols, C1-C5 case contains two active ingredients: ethanol (PC Code 001501) and isopropyl alcohol (PC Code 047501). The Reregistration Eligibility Decision (RED) for aliphatic alcohols, C1-C5, was published in 1995. The aliphatic alcohols, C1-C5, registration review case contains all C1-C5 alcohols because they are all water-soluble and are expected to be similar. The remaining alcohol groups, C6-16, reregistration case 4004 for which a RED was completed in 2007, is addressed under a separate registration review case located in docket EPA-HQ-OPP-2016-0261 at www.regulations.gov and is scheduled to be published in September 2016.The first pesticide product containing ethanol was registered in the United States on April 21, 1948 for use as a glassware sanitizer in eating establishments and as a hard non-porous surface disinfectant and bacteriocide in eating establishments and institutional premises. There are currently 71 registered active products containing the active ingredient ethanol. End use products containing the chemical ethanol are registered for use as surface disinfectants in use sites such as agricultural premises and equipment, medical premises and equipment, industrial areas and residential and public access areas. Ethanol is also registered for use in antifouling paints for use on boats bottoms and boat running gear below the water line.

End use products are also registered for use in aquatic industrial processes and water systems such as cooling towers as well as pulp and paper mill process water systems. In addition to being

registered for use in human drinking water systems, ethanol is also registered for use in products used in pools, hot tubs and spas. Ethanol containing products are also registered for use in aquatic areas such as commercial fishery water systems and fish containing lakes, ponds and reservoirs. There are two registered food uses for this chemical. One is for the sanitization of food eggs and the other is as a post-harvest treatment for specific fruits and vegetables.

Products containing ethanol also are registered for use as a plant growth regulator for use as a ripening agent for avocados, bananas, citrus fruits, kiwifruit, mangoes, melons, papayas, pears, persimmons, pineapples, stone fruits (nectarine, peach, and plum), tomatoes, walnuts, and flue-cured tobacco/cigar/cigar wrapping. The receptors in fruits and vegetables absorb free atmospheric ethylene molecules, and this in turn accelerates the ripening process. Fruits and vegetables produce ethylene gas naturally, and reabsorb the gas to stimulate the production of more; as this is the process by which ripening occurs. Ethanol is converted to ethylene gas, and the gas is pumped into ripening rooms. Due to the product based conversion of ethanol to ethylene gas, there are no expected exposures to ethanol on the raw agricultural commodity, (RAC) and residual ethylene gas is not expected.

The first product containing isopropyl alcohol (isopropanol) was registered on March 5, 1948 and is registered for use as a glassware sanitizer in eating establishments and as a hard non-porous surface disinfectant and bacteriocide in household, commercial and institutional premises. There are currently 32 registered products containing the active ingredient isopropyl alcohol. Products containing isopropyl alcohol are also registered for use in spray, ready to use solution and impregnated wipe forms. End use products containing the chemical isopropyl alcohol are registered for use as porous (fabrics, mattresses, etc.) and non-porous surface disinfectants in use sites such as agricultural premises and equipment, industrial areas and residential and public access areas. Products containing isopropyl alcohol are also registered for use in/on medical premises and equipment and veterinary premises as well as in/on salon and barber shop areas and utensils as well as ultra-sonic cleaners and for pre-cleaning of medical instruments prior to disinfection. In addition, isopropyl alcohol containing products are also used in non-pesticidal application as a deodorizer in air fresheners. Products containing it are also registered for use in retail and institutional food establishments, food processing plants and other health department regulated food facilities.

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for aliphatic alcohols, C1-C5 (case 4003). The following timeline highlights significant events that have occurred during the registration review of this case:

- July 6, 2012 – Publication of aliphatic alcohols, C1-C5 Summary document, including the Preliminary Work Plan (PWP), was issued for a 60-day public comment period.

- December 27, 2012 – Final Work Plan (FWP) for aliphatic alcohols, C1-C5 was posted. The comments received during the initial public comment period did not affect the data needs, work plan and timeline described in the PWP.

- The FWP noted that no additional data were anticipated to be needed for the aliphatic alcohols, C1-C5 registration review because sufficient information was available to support a registration review decision. Therefore, no Generic Data Call-In (GDCI) was needed for this case.

- Risk Assessment – the agency did not conduct ecological or human health risk assessments for aliphatic alcohols, C1-C5.

- March/April 2016 – The agency published the aliphatic alcohols, C1-C5 *Proposed Interim Registration Review Decision* in the docket (EPA-HQ-OPP-2012-0340) for a 60-day public comment period. No comments were received.

- September 2016 - The agency is now publishing the aliphatic alcohols, C1-C5 *Interim Registration Review Decision* in the docket (EPA-HQ-OPP-2012-0340).

II. Scientific Assessment

A. Human Health Assessment

A summary of the agency's human health assessment is presented below. For a detailed discussion of the human health assessment for aliphatic alcohols, C1-C5, see *Aliphatic Alcohols, C1-C5: Human Health Effects Scoping Document for the Registration Review Decision* dated April 16, 2012, available in the public docket EPA-HQ-OPP-2012-0340, at http://www.regulations.gov/.

1. Risk Conclusions

No human health risk assessment has been performed for aliphatic alcohols, C1-C5. Human health risk assessments were not required at the time of the RED in 1995 and registration review in 2012 because the agency determined that toxicological criteria were not triggered and that the exposure and risk from the active ingredients were not significant when compared to the frequent intentional human exposures resulting from non-pesticidal uses.

The agency does not need to require additional human health data for use in this registration review for aliphatic alcohols, C1-C5. The registered uses of the aliphatic alcohols, C1-C5 are not expected to result in contamination of surface water or ground water. Based on the antimicrobial use patterns of these chemicals as well as the fate property of rapid volatilization from the treated surface, it has been determined that residues of ethanol and isopropyl alcohol, along with byproducts resulting from degradation, are not expected to migrate through wastewater treatment facilities into drinking water or residential groundwater wells or to be present in measurable amounts in an occupational or residential setting.

2. Human Incidents

There is no human incident information in the agency's incident data system (IDS) from 1993 to August 2, 2016.

3. Tolerances

There are no EPA established tolerances or exemptions from tolerances identified for isopropyl alcohol. Ethanol has three inert exemptions from the requirement of a tolerance in 40 CFR 180.910, -.930, and -.940. Because of these chemicals' use patterns, volatility, ready biodegradability, and low toxicity, residues are not expected, and therefore, no tolerances or exemptions from tolerances for registered uses of ethanol and isopropyl alcohol are necessary.

4. EPA Not Relying on Human Studies

The Human Health Scoping Document noted that EPA was considering a 21-day dermal irritation study by Phillips et al., 1972[1], which compares rabbit and human skin response to certain irritants and concluded no dermal irritation. However, EPA has decided that this study is not needed to make a determination for registration review, and EPA is not relying on this study or its resulting data in any regulatory action or determination under FIFRA. Because the agency is not relying on the data, EPA is not required to submit this study to the Human Studies Review Board (HSRB) for review.

B. Environmental Assessment

A summary of the agency's environmental fate assessment is presented below. For a detailed discussion of the environmental assessment for aliphatic alcohols, C1-C5, see *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document in Support of Registration Review of Aliphatic Alcohols, C1-C5 (Ethanol and Isopropyl Alcohol)* dated May 31, 2012, available in the public docket EPA-HQ-OPP-2012-0340, at http://www.regulations.gov/.

1. Risk Conclusions

Environmental Fate and Exposures. The agency does not need to require additional environmental fate data for use in the aliphatic alcohols, C1-C5 registration review case. There is sufficient information in the public literature on the fate of aliphatic alcohols in the environment. Aliphatic alcohols chemistry is known and well documented in the open literature. Although the aliphatic alcohols are expected to be stable in water under typical use conditions, the compounds are not hazardous to the environment because they are readily biodegradable, a nutrient for microbes, and a metabolite of microbes.

Ecological Assessment. The most recent qualitative ecological risk assessment was performed for aliphatic alcohols, C1-C5 in support of the 1995 RED. The agency does not need to require additional ecological data and no additional ecological risk assessment was necessary for the registration review of aliphatic alcohols, C1-C5. The use patterns will lead to little, if any, exposure to non-target organisms. In addition, both alcohols are highly volatile, which supports the conclusion that exposure to terrestrial and aquatic nontarget organisms would be minimal.

[1]Phillips, L., Steinberg, M., Laibach, H.I., Akers, W.A., A comparison of rabbit and human skin response to certain irritants. Tox. Appl. Pharm. 1972;21(3):369-382.

2. Ecological Incidents

For the period from 1993 to August 2, 2016, there is no ecological incident information on the aliphatic alcohols, C1-C5, case in the agency's incident database.

C. Endangered Species Assessment

There is no reasonable expectation for any registered use of aliphatic alcohols, C1-C5 to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of critical habitat is expected from the use of aliphatic alcohols, C1-C5. Based on ethanol and isopropyl alcohol's use patterns, volatility, ready biodegradability, and low toxicity, and the use of these compounds as a nutrient source by microbes, EPA has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required.

D. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As required by FFDCA section 408(p), aliphatic alcohols, C1-C5 is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. Ethanol and isopropyl alcohol are not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP.

A second list of chemicals identified for EDSP screening was published on June 14, 2013[2] and includes some pesticides scheduled for registration review and chemicals found in water. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[3]

In this interim decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of aliphatic alcohols, C1-C5. Before completing this registration review, the agency will make an EDSP FFDCA section 408(p) determination.

III. Interim Decision

A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the agency is issuing this interim decision document for aliphatic alcohols, C1-C5. EPA's Registration Review Interim Decision determination for aliphatic alcohols, C1-C5, is that the pesticide meets the standard for registration under FIFRA. Also, as discussed in the Human Health Scoping Document and further in Section IV.C., EPA determined that based on the use patterns and chemical characteristics, the label restrictions for hard surfaces that will contact food are no longer appropriate. EPA recommends that any labels that contain this language be amended to delete this language. In addition, EPA does not expect aliphatic alcohols, C1-C5, to have direct or indirect adverse effects to non-listed and listed species or to adversely modify any designated critical habitat for such species and has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species. This interim decision does not cover the EDSP component of the aliphatic alcohols, C1-C5, registration review case. The agency is issuing an interim decision pending the evaluation of potential endocrine disruptor risk.

IV. Next Steps and Timeline

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of the interim decision for the aliphatic alcohols, C1-C5 case. A final registration review decision for the aliphatic alcohols, C1-C5 case will depend upon the result of an EDSP FFDCA section 408(p) determination.

[2] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

[3] http://www.epa.gov/endocrine-disruption

B. Implementation of Mitigation Measures

There are no mitigation measures or required label amendments associated with this Interim Decision.

C. Recommended Labeling Changes

In the RED, the specified use limitations included:

> "Not to allow the product to result in contact with foods/drinks/feeds or surfaces that they may contact; and to protect foods/drinks/feeds or surfaces during treatment by removing or covering them. Any contaminated food/drink/feed contact surfaces should be washed with a suitable cleaning product and rinsed with potable (drinking) water before using. Treat food/drink/feed processing areas only when the facility is not in operation."

These use limitations are conflicting as products containing ethanol and isopropyl alcohol are registered for use to sanitize or disinfect hard surfaces that will contact food items. Based on ethanol and isopropyl alcohol's use patterns and chemical characteristics, the restrictions are no longer appropriate. EPA recommends that any labels that contain this language be amended to delete this language.